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November 20, 2000

Janet Woodcock, MD
Food and Drug Administration
Dockets Management Branch
Department of Health and Human Services, Room 1-23
12420 Parklawn Drive
Rockville, Maryland 20857

Dear Dr. Woodcock:

RE: Docket #00P-1499/CP1

I am writing you this letter to share my experience with Lotronex (Alosetron) with you. Our office represents one of the investigator sites, and I have used the medication since released on the market in approximately 80 to 100 patients. All these patients were suffering from diarrhea prone irritable bowel syndrome, some of them experiencing very debilitating symptoms with severe cramping pain, stool frequency, urgency, and rectal pain. Many of these patients felt that their life quality was severely impacted to the point that they had to stop working or to interrupt their studies and drop out of school.

In my experience the medication has worked very well; and many of these people now are back in their jobs, feeling that their lives are almost back to normal. They are very grateful. The only side effect that I have seen has been constipation in the first few weeks. In those cases, I usually reduced the dose to once a day or maybe once every other day and will ask patients to take some extra fiber or Milk of Magnesia or Miralax in order to improve their stooling.

In some patients, the constipation effect was not acceptable; and the drug had to be discontinued. One patient had experienced aggravation of her abdominal cramps, and we had to stop the Lotronex.

In summary, the majority of the patients experienced a beneficial effect and sometimes a very dramatic improvement of their symptoms. I have not seen any serious side effects, whatsoever.

I hope this information is helpful to you while you are reviewing this medication and the requests to have it withdrawn from the market.

With personal regards,

Stefan P. Marcuard, MD, FACP, Gastroenterology
SPM/ge

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